

DS a middle elongated portion that is at least partly inserted inside the body, comprising a signal conduit that electronically connects the energy source and the fluorescent light source.

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DS 41. (Twice Amended) An interventional device, comprising:
a distal portion comprising a spark gap module for placement inside a body;
a proximal end connected to an energy source; and
a middle elongated portion that is at least partly inserted inside the body, comprising a signal conduit that electronically connects the energy source and the spark gap module.

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DS 47. (Twice Amended) An interventional device, comprising:
a distal portion comprising an incandescent lamp for placement inside a body and for generating short duration high intensity light waves;
a proximal end connected to an energy source; and
a middle elongated portion that is at least partly inserted inside the body, comprising a signal conduit that electronically connects the energy source and the incandescent lamp.

REMARKS

Claims 1, 3-12, 14-17, 20-30, 32-44, 47-50, and 52-53 were pending in the application, all of which were rejected in the Office Action. Claims 3 and 16 are hereby canceled without prejudice to future prosecution. Claims 1, 17, 20, 32, 41, and 47 are amended by the present Amendment. Upon entry of the present Amendment, claims 1, 4-12, 14-15, 17, 20-30, 32-44, 47-50, and 52-53 are pending and presented for reconsideration. Applicant respectfully submits that no new matter is introduced by the present Amendment. A marked-up copy of the amended and canceled claims, and a clean copy of all pending claims, as amended herein, are attached.

Claim 1 is hereby amended to recite the limitations formerly contained in claim 3. Claim 17 is amended to depend from claim 1. Support for the amendment may be found in the

Specification at, for example, pages 12-13. Claims 20, 32, 41, and 47 are amended by deleting the term “of variable length”.

Rejection of Claims 16, 17, 20-30, 32-44, 47-50, 52 and 53 under 35 U.S.C. § 112, second paragraph

Claims 16, 17, 20-30, 32-44, 47-50, 52 and 53 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite due to failure in pointing out and distinctly claiming the subject matter which Applicant regards as the invention. In particular, the Office Action indicates that antecedent basis is lacking for the claim language “of variable length” in the independent claims of the above claims, namely, claims 16, 20, 32, 41, and 47. Applicant has canceled claim 16 without prejudice to future prosecution, and amended claims 20, 32, 41, and 47 by deleting the language “of variable length” and respectfully submits that this basis for rejection is overcome by the amendment.

The Office Action has also objected to the term “electronically connected” in claim 16. As claim 16 is canceled, this rejection is rendered moot. Therefore, Applicant respectfully submits that the instant amendment has overcome the rejections under 35 U.S.C. § 112, second paragraph.

Rejection of Claims 16, 17, 20-30, 32-44, 47-50, 52 and 53 under 35 U.S.C. § 112, first paragraph

Claims 16 and 17 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art of the inventor’s possession of the claimed invention at the time of the filing. In particular, the Office Action interprets the “x-ray generating light source” recited in claims 16 and 17 as cavitation bubbles, and asserts that no electrical connection is disclosed in the specification as leading to the cavitation bubbles. Applicant has canceled claim 16, and has amended claim 17 to depend from claim 1. The limitation of electronic connection to a light source is no longer present in amended claim 17, and the term “light source” has been changed to “light module,” making it clearer that the recited light module is not directed to cavitation bubbles, but mechanical structures such as those described in the specification at, e.g., pages 12

and 13, and Fig. 4. As such, the specification clearly describes the device recited in the amended claim 17. Therefore, Applicant respectfully submits that the rejections under 35 U.S.C. § 112, first paragraph, have been overcome.

Rejection of Claims 1, 5-8, 10-12 and 15-17 under 35 U.S.C. § 102

Claims 1, 5-8, 10-12 and 15-17 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 4,893,614 to Takayama et al. ("Takayama"). Claim 16 is also rejected under the same provision over U.S. Patent No. 5,090,043 to Parker *et al.* ("Parker").

Amended claim 1 recites an interventional device including a sonoluminescent light module for placement inside a body. The light module includes an acoustic transducer, a housing and a lens. Without acquiescing to the Examiner's arguments, Applicant has amended claim 1 to recite that the acoustic transducer includes a piezoelectric element and a wave matching layer.

Takayama describes an extracorporeal lithotripter including a pseudo-ellipsoidal shaped housing filled with liquid. A shock wave is generated at a first focus of the pseudo-ellipsoid, resulting in impact at the second focus where the calculus is positioned. See Abstract and Summary of Invention.

Takayama does not teach or suggest a light module that includes a piezoelectric material and a wave matching layer. To generate a shock wave, Takayama describes using a microexplosive, a spark gap generator, a supersonic wave generator or a laser beam (column 2). The microexplosive is used in combination with a trigger means (column 2, lines 51-58). The spark gap generator includes an electric source and two spaced apart plates (column 2, lines 33-38). The supersonic wave generator is illustrated in FIG. 4 and described briefly in column 8, lines 3-7. None of the apparatus used to generate the shock waves in Takayama includes a piezoelectric material or a wave matching layer to achieve high efficiency in energy transfer. This is partly because Takayama is not concerned with generating light from sound waves but with transmitting shock waves from outside the body to a point inside the body. The operation of Takayama's device relies on the pseudo-ellipsoidal shape of its liquid container, and the flexibility of the container's material to position a target calculus at the second focus of the pseudo-ellipsoid. See Abstract and Summary of Invention.

Applicant also respectfully invites the Examiner's attention to some of the additional limitations recited in claims 5-8, and 10-12, which are claims that depend from claim 1. For example, claim 6 recites the additional limitation that the distal end of the housing of the sonoluminescent light module is open in order to focus sound waves in body tissues. The lithotripter device in Takayama uses a liquid container that is to be placed next to a human body (columns 1-2), and the distal end of the container cannot be open or else the liquid would leak out, rendering the device useless. Instant claim 8 recites the additional limitation that the acoustic conducting medium comprises a solid substance or target on which sonoluminescent effect can be observed. In contrast, Takayama only uses a liquid in its shock wave generation chamber, and does not use a solid substance or target on which sonoluminescent effect can be observed.

Claim 16 has been canceled without prejudice, therefore, rejections of claim 16 over Takayama or over Parker is moot. Claim 17 has been amended to depend from claim 1. Because Takayama does not teach or suggest one or more aspects of amended claim 1, amended claim 17 is also patentable under 35 U.S.C. § 102 over Takayama.

In light of the above amendments and remarks, Applicant respectfully submits that the rejections under 35 U.S.C. § 102 should be reconsidered and withdrawn.

Rejection of Claims 3, 4, 9, 14, 20-30, 32-44, 47-50, and 52-53 under 35 U.S.C. § 103(a)

Claims 3, 4, 9, 14, 20-30, 32-44, 47-50, and 52-53 were rejected under 35 U.S.C. § 103(a) over Takayama in view of U.S. Patent No. 5,601,526 to Chapelon *et al.* ("Chapelon"). Claim 3 has been canceled without prejudice and only the remaining pending claims will be discussed below.

Chapelon describes a treatment device that delivers ultrasonic waves that produce thermal and cavitation effects to destroy ailing tissues such as tumors (column 1). The Office Action suggests that Chapelon's device can be intracavity and this aspect can be used to modify the extracorporeal aspect of the device in Takayama.

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally

available in the art, to modify the reference or to combine reference teachings. MPEP 706.02(j). The use of an extracorporeal procedure instead of an intrusive one was an advance in lithotripsy, offering the obvious advantages of minimizing patient risk and discomfort, and the extracorporeal procedure has become “the preferred method of treatment.” Vona et al., “A Test of The Hypothesis That Cavitation at the Focal Area of an Extracorporeal Shock Wave Lithotripter Produces Far Ultraviolet and Soft X-ray Emissions,” *J. Acoust. Soc. Am.* 98 (2), 706, 706, August 1995 (“Vona”). Absent specific motivation to revert the trend and to use the shock wave treatment inside the body, one skilled in the art would not modify the extracorporeal aspect of the device in Takayama. In fact, Takayama specifically teaches away from such a modification by pointing out extracorporeal treatment’s advantages in avoiding physical or mental suffering in the patient and in allowing quick recovery (column 1, lines 31-36).

Additional evidence of teaching away from the suggested combination exists with respect to claims 4, 9, and 14 of the present Application. Claim 4, 9 and 14 depend from amended claim 1, which, in turn, recites an interventional device that includes a sonoluminescent light module. Chapelon does not teach or suggest a sonoluminescent light module. However, the Office Action, based on Vona, suggests that the device in Takayama inherently produces sonoluminescence. Vona describes testing a hypothesis that “the violent collapse of microbubbles in water in the focal area of an extra-corporeal shock wave lithotripter (ESWL) can generate biologically damaging far uv and soft x-ray photons.” (See Abstract.) Vona repeatedly warns that such high-energy photons of uv or soft x-ray produce harmful biological effects both *in vivo* and *in vitro*. See Introduction. This further teaches one skilled artisan away from modifying the Takayama device for intracorporeal use.

To establish a *prima facie* case of obviousness, there also must be a reasonable expectation of success. MPEP 706.02(j). Takayama describes the use of shock waves in disintegrating isolated stones. Chapelon describes the thermal and cavitation effects of ultrasonic waves in ablating selected tumor tissues. The physical and chemical properties of calcified stones and tumorous tissues being vastly different, there is no reason to expect ablation of soft tissues with the aid of a cooling system, as described in Chapelon, would be successful in disintegrating stones targeted by Takayama.

In light of the above arguments, Applicant respectfully submits that the combination of the prior art references on record is improper and therefore respectfully requests that the rejections under U.S.C. § 103 should be reconsidered and withdrawn.

INFORMATION DISCLOSURE STATEMENT (IDS)

Applicant notes that initialed copies of PTO-1449 forms for IDSs and Supplemental IDSs submitted by Applicant on September 2, 1997, October 31, 1997 and June 3, 1998, together listing references AA-AAZ, BA-BT, and CA-CM, have not been returned and hereby respectfully requests such action by the Examiner.

CONCLUSION

Applicant requests that the Examiner reconsider the application and claims in light of the foregoing Amendment and Response, and respectfully submits that the pending claims (i.e., 1, 4-12, 14-15, 17, 20-30, 32-44, 47-50, and 52-53), as amended, are in condition for allowance. If, in the Examiner's opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues, and to work with the Examiner toward placing the application in condition for allowance.

Applicant believes that no additional fees are necessitated by the present Amendment. However, in the event that any additional fees are due, the Commissioner is


hereby authorized to charge any such fees to Attorney's Deposit Account No. 20-0531.

Respectfully submitted,

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Reg. No.: 38,349

Tel. No.: (617) 248-7362
Fax No.: (617) 248-7100

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Michael J. Twomey
Attorney for Applicant
Testa, Hurwitz, & Thibault, LLP
High Street Tower
125 High Street
Boston, Massachusetts 02110

U.S.S.N.: 08/922,263

"Interventional Photonic Energy Emitter System" by Crowley

Marked-up Copy of Claim Amendment

1. (Thrice Amended) An interventional device, comprising:
a sonoluminescent light module for placement inside a body, the module comprising
 - (i) an acoustic transducer comprising a piezoelectric element and a wave matching layer for generating sound waves;
 - (ii) a housing enclosing an acoustic conducting medium, the acoustic conducting medium positioned in a pathway of the sound waves generated by the acoustic transducer, at least a portion of the housing being optically transparent; and
 - (iii) a lens for focusing the sound waves generated by the acoustic transducer in the acoustic conducting medium, whereby sonoluminescent light is generated.
3. (Cancelled) ~~The interventional device of claim 1 wherein the acoustic transducer comprises a piezoelectric material and a wave matching layer.~~
16. (Cancelled) ~~An interventional device, comprising:
a distal portion comprising an x-ray generating light source for placement inside a body;
a proximal end connected to an energy source; and
a middle elongated portion of variable length that is at least partly inserted inside the body, comprising a signal conduit that electronically connects the energy source and the x-ray generating light source.~~
17. (Amended) The interventional device of claim ~~16~~1 wherein the ~~x-ray generating sonoluminescent light source~~ comprises a sonoluminescent light source module is capable of generating x-ray.
20. (Twice Amended) An interventional device, comprising:
a distal portion comprising an arc lamp for placement inside a body;
a proximal end connected to an energy source; and

a middle elongated portion of ~~variable length~~ that is at least partly inserted inside the body, comprising a signal conduit that electronically connects the energy source and the arc lamp.

32. (Twice Amended) An interventional device, comprising:

a distal portion comprising a fluorescent light source for placement inside a body;

a proximal end connected to an energy source; and

a middle elongated portion of ~~variable length~~ that is at least partly inserted inside the body, comprising a signal conduit that electronically connects the energy source and the fluorescent light source.

41. (Twice Amended) An interventional device, comprising:

a distal portion comprising a spark gap module for placement inside a body;

a proximal end connected to an energy source; and

a middle elongated portion of ~~variable length~~ that is at least partly inserted inside the body, comprising a signal conduit that electronically connects the energy source and the spark gap module.

47. (Twice Amended) An interventional device, comprising:

a distal portion comprising an incandescent lamp for placement inside a body and for generating short duration high intensity light waves;

a proximal end connected to an energy source; and

a middle elongated portion of ~~variable length~~ that is at least partly inserted inside the body, comprising a signal conduit that electronically connects the energy source and the incandescent lamp.